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QPS White Paper

Overcoming Pediatric Trial Challenges

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Overcoming the Challenges of Participating in a Pediatric Trial

Since the enactment of the FDA Safety and Innovation Act (FDASIA) in 2012, the demand for pediatric clinical trials has increased. Pediatric trials are specialized and unique, and they are becoming more popular, particularly with companies that want to extend their patents to include pediatric patents. According to the FDA, only about 20 percent of drugs have been labeled for pediatric patients. The potential is high to get new drugs approved for use in pediatrics. And QPS is pleased to support its partners in conducting pediatric clinical trials to test how drugs work in children.

As the number of pediatric trials being conducted increases, there are several challenges confronting parents, guardians, patients and pharmaceutical companies. One of the biggest of these issues is that it is difficult to enroll participants in pediatric trials. However, these five strategies can help make it easier to enroll trial participants and complete successful trials.

1. Reserve Budget for Trial Advertising and Patient Recruitment

Children tend to be more difficult to recruit for trial studies than adults, and attracting enough participants to make a study viable can be even more of a challenge. Parents may be unwilling to submit their child to rigorous studies and treatments that are not yet proven to work. The exception to the rule may be in cases of rare diseases where there are not many alternatives available for treatment. However, because a majority of parents have concerns about outcomes and safety, convincing them to enroll their children in trials is difficult.

To help increase participation in pediatric trials, it is important to reserve budget for marketing and advertising. Setting aside budget to produce advertisements for television, radio, print or social media channels can help generate attention for trials and make recruitment easier. It will take additional money to have recruiters in place to work with families who respond to advertisements, answer their questions and enroll trial participants. It is important for pharmaceutical and biotech companies to allocate budget for trial advertising and patient recruitment so that studies can be viable.

2. Base Trial Timelines on What Works for Pediatric Patients

Another obstacle for pediatric clinical trials is patient availability. Children typically are not as readily available as adults due to their school schedules or even parents' work schedules, so this creates an issue of when to perform a study. To work around this, trials can be scheduled during breaks through the summer, spring or holidays. Trials may also need to be scheduled to allow children to participate after school and on weekends. It is important to be realistic when determining how long a study will last. For pediatric patients, shorter studies are better. For example, a study might be every weekend for three months. It just depends on the treatment or what the protocol entails. Some studies might require just a single outpatient visit and then can be designed so the remainder of the trial is performed at home through entries in a diary. Flexibility is critical when trying to design trials that are suitable for pediatric patients.

In addition to helping with enrollment, careful consideration about the timing and overall length of pediatric trials may help prevent dropouts and boost trial completion rates. Pediatric patients, and their families, may not be able to tolerate lengthy trials. Limiting trials to a maximum of four or five months is ideal. It is important to also keep in mind that pediatric patients may be less tolerant of complex procedures that take place during long treatment sessions.

3. Require Permission from Only One Parent

Because children are not of legal age, they must have parental permission to participate in a clinical trial. In many situations, obtaining permission from two parents (rather than just one) can be difficult. To make the recruitment process easier, trials can be designed to require just one parent or guardian offering consent to participate.

4. Explore Pediatric-Friendly Trial Protocols

During a pediatric study, the placebo period in the blind trial may need to be shortened, and treatment can be offered to placebo recipients as an extension. In other words, at the end of the placebo trial, the participant would receive the actual drug as a treatment. Offering the guarantee of receiving the trial treatment is yet another way to prevent dropouts and help patients' parents feel more confident that participating in a trial is worthwhile.

Another way to simplify trials for participants is to require fewer clinical visits during the study. Pharmaceutical and biotech companies can explore opportunities to observe and capture information from pediatric trial participants outside of the clinical setting through various means. If a child is participating in a trial related to ADHD management and has been asked to record journal entries at home, it can reduce the number of clinical visits, while still capturing crucial data. Technology also provides opportunities to utilize monitoring devices, such as blood glucose and heart rate monitors, that allow pediatric patients to participate in trials with fewer in-person clinical visits.

5. Provide Support and a Comforting Environment for Caregivers

There is already enough stress on a child and family dealing with a disease or illness, so it is important that a trial does not add more stress. Ideally, a child and any accompanying family members will feel they have entered a warm and welcoming environment when they arrive at a clinic. While it requires planning to create a comfortable environment for children, their parents and siblings, it can make for a more pleasant experience for everyone.

Providing additional support to a trial participant's caregiver(s) may involve creating a designated area for siblings to play, watch TV, eat a snack or do homework. Or it could mean providing a space for parents to catch up on work while their child is getting treatment, or even just an area for family members to relax and visit comfortably while they wait. By providing a well-planned area for caregivers to maximize their time during clinical visits, it makes in-office treatments less inconvenient.

Conclusion

The demand for pediatric studies will continue to rise, but trial recruitment and enrollment does not need to be difficult. A few simple strategies can make all the difference in designing a successful pediatric trial. Selecting a CRO with knowledge of these strategies and experience conducting successful pediatric trials is important.

QPS Experience

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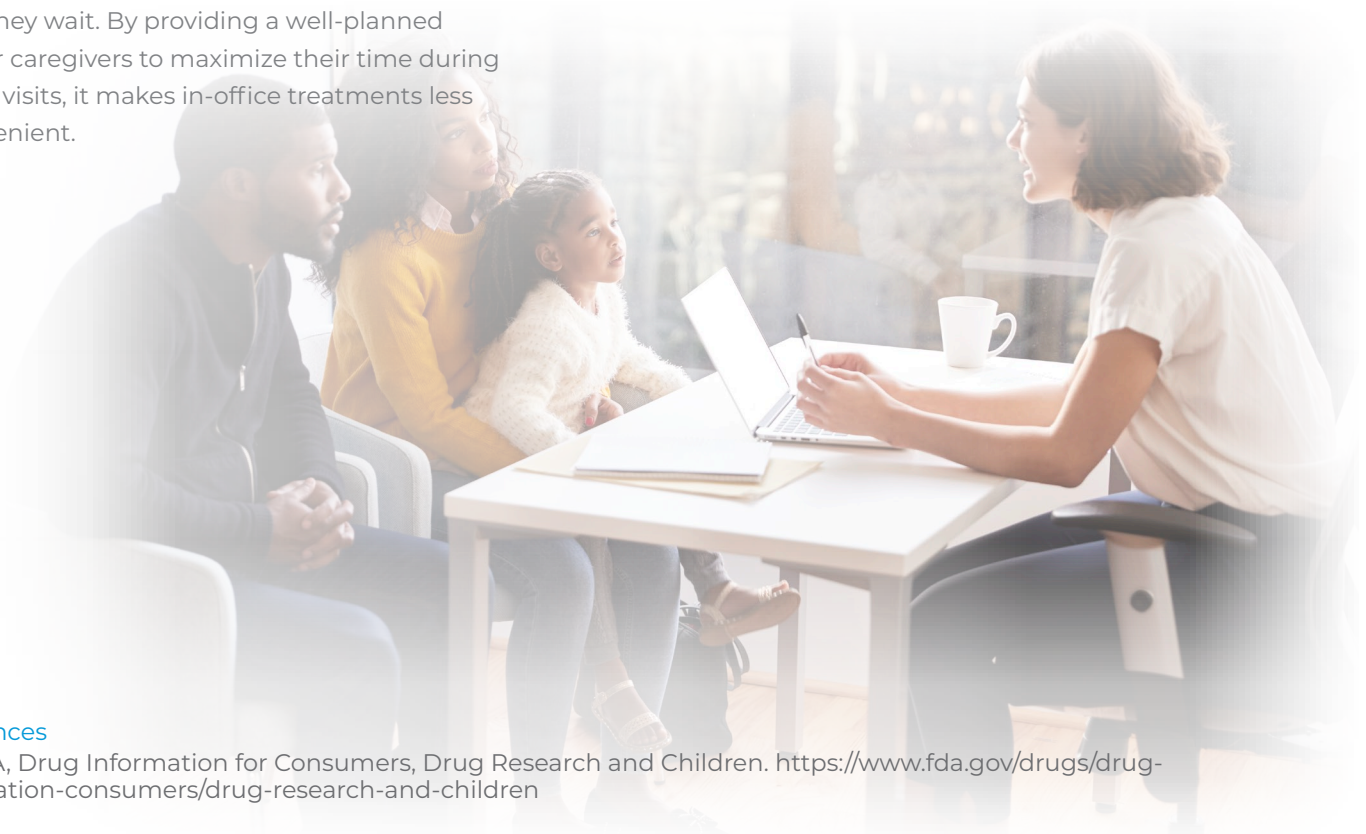

References

US FDA, Drug Information for Consumers, Drug Research and Children. https://www.fda.gov/drugs/drug-information-consumers/drug-research-and-children